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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,424	07/22/2005	Klaus Henning	09600-00028-US	6261

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EXAMINER

OLSON, ERIC

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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01/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,424

Applicant(s)

HENNING, KLAUS

Examiner

Eric S. Olson

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's communication submitted November 13, 2007 wherein claims 1, 7, and 10-13 are amended and claim 3. This application is a national stage application of PCT/EP03/08411, filed July 30, 2002, which claims priority to foreign application DE10237442.2, filed August 16, 2002.

Claims 1, 2, and 4-13 are pending in this application.

Claims 1, 2, and 4-13 as amended are examined on the merits herein.

Priority

An English translation of foreign priority document DE10237422.2 has been provided in the response filed November 13, 2007. The document is seen to provide support under 35 USC 112 for the claimed subject matter. Therefore the instant application is entitled to a foreign priority claim of August 16, 2002.

Applicant's amendment, submitted November 13, 2007, with respect to the rejection of instant claims 10 and 11 under 35 USC 112, second paragraph, for reciting the indefinite phrase, "conventional additions" has been fully considered and found to be persuasive to remove the rejection as this phrase has been removed from the claims. Therefore the rejection is withdrawn.

Applicant's foreign priority document, submitted November 13, 2007, with respect to the rejection of instant claims 1, 3, 5, 11, and 13 under 35 USC 102(b) for being

anticipated by Sommermeyer et al. '207, has been fully considered and found to be persuasive to remove the rejection as the application is entitled to a foreign priority claim prior to the publication date of Sommermeyer et al. '207. Therefore the rejection is withdrawn.

Applicant's arguments submitted November 13, 2007, with respect to the rejection of instant claims 1, 3, 5, and 10 under the doctrine of obviousness-type double patenting as claiming the same invention as claims 1, 6, and 7 of copending application 10/486943, have been fully considered and found to be persuasive to remove the rejection as the two applications are seen to have no common inventor or assignee. Therefore the rejection is withdrawn.

The following grounds of rejection of record in the previous office action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-8, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommermeyer et al. (US patent 5218108, of record in previous action, herein referred to as Sommermeyer et al. '108) in view of Antrim. (US patent

publication 2002/0065410, patent application 09/725990, of record in previous action) Sommermeyer et al. '108 discloses a hydroxylethyl starch having properties suitable for use as a plasma expander. (column 3, lines 25-62) In particular, an embodiment is disclosed having a mean molecular weight of 234000, a molar hydroxyethyl substitution degree of 0.26, and a C2-C6 ratio of 9.34. (column 5, lines 18-26) Also, claim 2 claims a starch with a mW of 80000-400000, a substitution degree of 0.2-0.4, and a C2/C6 ratio of 8-20. Sommermeyer et al. '108 does not disclose such a starch also having a degree of branching in the range of 8-20 mol %.

Antrim discloses a highly branched starch that is more stable in solution, and thus less liable to aggregate, haze, or precipitate. (p. 1, paragraphs 0006, 0007, and 00010) In a particular preferred embodiment the degree of branching is 8-10% or greater than 10%. (p. 2, paragraph 0012)

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the hydroxylethyl starch of Sommermeyer et al. '108 with a degree of branching of 8-10% or greater, up to 20%, and a C2/C6 ratio of 8-9, and to use it as a plasma expander. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications. One of ordinary skill in the art would reasonably have expected success because the modifications described by Sommermeyer et al. '108 can be made to a variety of starches. With regard to the C2/C6 ratio, when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re*

Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted November 13, 2007, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Sommermeyer et al. '108 teaches away from making the modifications discussed by Antrim, because the hydroxyethyl starches of Sommermeyer et al. '108 are already described as being stable in solution for a relatively long time. However, this vague statement is not sufficient to provide a teaching away from the claimed invention. In order to teach away from a modification, the prior art must state not only that the modification is not necessary, but that it is in fact not at all beneficial, or that it is positively harmful. While it is clear from the prior art that one can make a hydroxyethylstarch-based plasma expander with a starch having a degree of branching below that claimed in the instant claims, it is not therefore the case that there would be no motivation to further improve the stability, either *in vivo* during use or *in vitro* during storage, of the starches of Sommermeyer et al. '108. In fact, one of ordinary skill in the art would reasonably consider the elimination of retrogradation behavior to be a desirable result, and a sufficient motivation for preparing starches having a high degree of branching as discussed by Antrim.

Therefore the rejection is deemed proper and made **FINAL**.

Claims 1, 2, 4, 6-8, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommermeyer et al. (US patent 6284140, of record in previous office action, herein referred to as Sommermeyer et al. '140) in view of Antrim. (US patent publication 2002/0065410, patent application 09/725990, of record in previous action) Sommermeyer et al. '140 discloses a dialysis solution containing a hydroxylethyl starch having a molecular weight of 10000-150000, preferably 10000-55000, more preferably 20000-29000, most preferably 29000, a molar degree of substitution of 0.10-0.24, and a C2/C6 ratio of 8-25. (column 2, lines 10-38) This solution is stable for long periods of time and does not disturb residual kidney function. (column 4, lines 37-50) Sommermeyer et al. '140 does not disclose such a starch having a degree of branching of 8-20% or a C2/C6 ratio of 8-9.

Antrim discloses a highly branched starch that is more stable in solution, and thus less liable to aggregate, haze, or precipitate. (p. 1, paragraphs 0006, 0007, and 00010) In a particular preferred embodiment the degree of branching is 8-10% or greater than 10%. (p. 2, paragraph 0012)

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the hydroxylethyl starch of Sommermeyer et al. '140 with a degree of branching of 8-10% or greater, up to 20%, and a C2/C6 ratio of 8-9, and to use it in a peritoneal dialysis solution. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications. In particular, they are less likely to precipitate or otherwise display

undesirable physical properties in the peritoneal cavity during long dwell times. One of ordinary skill in the art would reasonably have expected success because the modifications described by Sommermeyer et al. '140 can be made to a variety of starches. With regard to the C2/C6 ratio, when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted November 13, 2007, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Sommermeyer et al. '140 teaches away from making the modifications discussed by Antrim, because the hydroxyethyl starches of Sommermeyer et al. '140 are already described as being stable in solution for a relatively long time in Sommermeyer et al. '108, which is incorporated by reference. However, this vague statement is not sufficient to provide a teaching away from the claimed invention. In order to teach away from a modification, the prior art must state not only that the modification is not necessary, but that it is in fact not at all beneficial, or that it is positively harmful. While it is clear from the prior art that one can make a hydroxyethylstarch-based peritoneal dialysis solution with a starch having a degree of branching below that claimed in the instant claims, it is not therefore the case that there would be no motivation to further improve the stability, either *in vivo* during use or *in vitro* during storage, of the starches of Sommermeyer et al. '140. In

fact, one of ordinary skill in the art would reasonably consider the elimination of retrogradation behavior to be a desirable result, and a sufficient motivation for preparing starches having a high degree of branching as discussed by Antrim.

Therefore the rejection is deemed proper and made **FINAL**.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Sommermeyer et al. '108 in view of Antrim or Sommermeyer et al. '140 in view of Antrim, as applied to claims 1, 2, 4-8, and 10-13 above, and further in view of Naggi et al. (PCT international publication WO00/33851, of record in previous action) the disclosures of Sommermeyer et al. '108 in view of Antrim and Sommermeyer et al. '140 in view of Antrim are discussed above. None of these references disclose a starch in which the reducing end has been inactivated by oxidation or reduction.

Naggi et al. discloses a sterilized peritoneal dialysis solution comprising a starch in which the reducing end has been inactivated by oxidation or reduction. (pp. 4-5) These starches have the advantage that they are stable under autoclaving and steam sterilization conditions. (p. 10, lines 15-18) This property is useful because it allows for high-temperature sterilization of the starch solutions without the production of formaldehyde. (p. 3, lines 14-24)

It would have been obvious to one of ordinary skill in the art at the time of the invention to oxidatively or reductively modify the reducing ends of the starches of any of the aforementioned references. One of ordinary skill in the art would have been motivated to modify the invention in this way because Naggi et al. discloses that doing

so allows the starch to be autoclaved without forming toxic degradation products such as formaldehyde. One of ordinary skill in the art would reasonably have expected success because oxidations and reductions are simple chemical transformations that can reasonably be applied to a wide number of starches using only simple and routine chemical procedures, and because the techniques of Naggi et al. are reasonably expected to be applicable to any polysaccharide with a reducing end.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted November 13, 2007, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those given above with respect to the rejections over Sommermeyer et al. '108 in view of Antrim or Sommermeyer et al. '140 in view of Antrim, and are not found to be persuasive for the same reasons. Therefore the rejection is deemed proper and made **FINAL**.

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.**

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

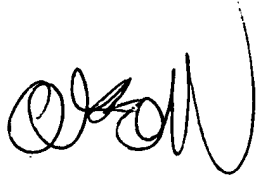
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
AU 1623
12/21/07



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 12/31/07
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